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(72) Inventor: Mas Gomez, Fco. José
F-46988 Paterna, Valencia (ES)

(71) Applicant: INDUSTRIAS QUIRURGICAS DE
LEVANTE, S.A.
46988 Paterna - Valencia (ES)

(74) Representative: Urizar Anasagasti, José Antonio
URYAS
P.O. Box 61051
28080 Madrid (ES)

(54) Modular design osseous substitution prosthesis

(57) Osseous substitution prosthesis of modular design adequate for the osseous substitutions of the femur proximal zone, up to the 2/3 of the upper portion of the femur, which has of a metaphisary component, of one or various accumulable diaphysis components and of an intramedullar stem, such that in order to join the metaphisary component, one or various diaphysis components and the intramedullar stem a screw which holds the prosthesis being screwed onto the intramedullar stem is used. The metaphisary component is unique and therefore common to all the interventions and has a medial opening, and the diaphisiary components vary in their lengths from one size to another in a small and fixed quantity rate such that the maximum error that might be committed is precisely the value of that very small established quantity rate. The intramedullar stem may be of different lengths and diameters which are chosen depending on the patient's medular canal diameter and on the bone quality; and in order to improve its fixation, once introduced in the healthy bone, cortical screws are used which hold transversally the lateral tongue of the stem to the bone.

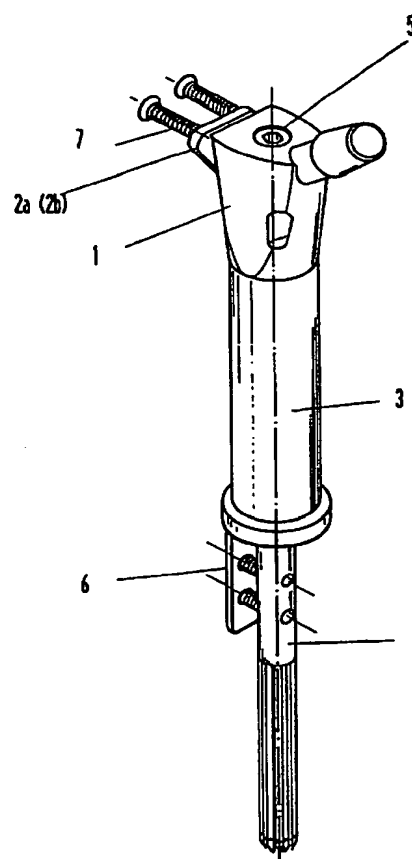


FIG. 1

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Descripti n

Object of the invention

The present invention refers to an osseus replacement prosthesis of modular design appropriated for femur proximal zones.

Background of the invention

The curative treatment of the primitive malign osseous tumors requires the chirurgical resection "in block" of the whole existing macroscopic disease at the moment of diagnosis.

The existing surgical proceedings to obtain said objective can be framed within two fundamental possibilities: the amputation or the limb preservation techniques.

During the recent years, the introduction of new diagnostical means by the image, and the use of the preoperative chemotherapy and radiotherapy have contributed to perform this type of surgery. For this reason, modern technics of limb rescue have been developed. In Spain, various articles have been recently published referring to this pathology type and reconstruction technics thereof.

The primitive osseous tumors, lay mainly on metaphisary level of the long bones, in their more fertile aspect. The reconstruction implies the question of the correction of the articular deficiency, which can only be effected by means of arthrodesis or arthroplasty; although if it is wished to reconstruct functionally the osseus defect, one must make use of an "artificial" arthroplasty (resection prosthesis) or a "natural" arthroplasty (osteoarticular osseous allograft).

With the appearing and development of the bones bands, the osteocartilageous allografts constitute "a priori" the most desireable solution, although there are still problems pending to be resolved, such as the preservation of the articular cartilage or of the articular denervation which lead to a similar situation as that of the neuropathical arthropaty.

The resection prosthesis are the alternative mostly used at present. Some 30 years ago chondrosarcomas and parostal osteosarcomas began to be used in benign tumors with local aggressivity or highly relapsy, such as the tumor with gigant cells, and in malign tumors of low grade.

Recent studies have shown an excellent local control of the disease, preserving the function. Harris, et al made a comparative study among patients who had been amputated and those to whom the limb had been preserved, finding similar functional results, but with a higher emotional acceptability in those to whom a conservative surgery had been submitted.

The recurrence percentage is similar among the amputated and those submitted to a conservative surgery; and also their survival is comparable.

The cosnervative surgery consists, nowadays, of two surgical proceedings: The first being the tumor resection, which is simply to be evaluated by the local recurrence rates. The second proceeding is the reconstruction, which comes to depend on the resected structures.

There is another application for the prosthesis of osseous resection which is the case of the revisions. At present there are thousands of persons who have been submitted in former years to a substitution of the hip articulation with a prosthesis, these prosthesis as the time goes by became loosened making necessary their substitution. In the case that the bone is in good conditions a prosthesis similar to the former one can be used, however the femur is partially destructed and the best solution is the partial resection of the bone and the substitution with a prosthesis of the type of the object of this invention.

The use of prosthesis for the substitution of the resected zone began with the use of prosthesis properly measured; these prosthesis are being used at present. Nevertheless, these prosthesis have some inconveniences:

- price
- long execution term
- the intraoperative resection must be adapted to the prosthesis

Therefore nowadays there is a tendancy toward modular prosthesis which are adaptable to the incidences of the surgery action.

To overcome these problems the so called "osseous substitution prosthesis" is proposed.

Description of Drawings

In order to better understand the object of the present invention a preferred practical embodiment of the same is represented in the accompanying drawing:

Figure 1 shows a perspective view of the assembled object of the invention.

Figure 2 shows a perspective view of each essential element which constitute the object of the invention, in explosion view.

Figure 3 corresponds to an additional mounting with two elements of the invention.

Practical embodiment of the invention

The osseous substitution prosthesis consists of the elements described hereinbelow, basing the design of said elements on the following characteristics:

1) The prosthesis is adequate for osseous substitutions in the femur proximal zones, up to the 2/3 of upper part of the femur.

2) The prosthesis is made of an Ti-6Al-4V alloy which is a material presenting many advantages with respect to others:

- high elasticity and fracture limit;
- elasticity module with half the value of steel and of Cr-Co-Mo
- very good biocompatibility
- stress limit higher than that of steel
- density half the value of steel and of Cr-Co-Mo

3) The prosthesis is designed such that its utilization is flexible and that during surgical intervention, any variation over what is scheduled is made possible. For that reason they are provided with a sole metaphisary component (1) which is common for every intervention. Depending on the length of the resection to be effected, one or various diaphysis components (3) are used, as these may be accumulated. The rate of increase from one size to a next one is of 20 mm, with which the maximum error that might be committed is of 20 mm. This error can be compensated by reducing the bone length a little more than what is strictly necessary and/or utilizing bar heads with different necks (1) and/or cups with various profiles with which the cited defect is corrected. There are 6 intramedullar stems (2 lengths and 3 diameters) which are chosen depending on the diameter of the patient's medullar canal and on the quality of the bone. Normally, long intramedullar stems are used in resection prosthesis and short intramedullar stems in tumorations.

In order to join the metaphisary component (1), one or various diaphysis components (3) and the intramedullar stem a screw is used which holds the prosthesis being screwed in the intramedullar stem. There are 11 union screws (5) which permit to utilize diaphysis components (3) from 0 to 200 mm.

4) The metaphisary component (1) has a medial opening to connect the ligaments and in the rear zone permits the annexation of the trochanter ligaments. This is achieved by screwing the fixation plate with the trochanter fixation screws (7). In the case where the trochanter can be saved, the trochanter fixation plate of trochanteral plate (2) is used, while if it cannot be saved, the ligaments are directly connected to the ligament fixation plate.

5) The intramedullar stem is introduced in the healthy bone and for improving its fixation cortical screws (6) are used which transversally fix the lateral tongue of the stem to the bone.

6) There is the possibility to make resections of the femur diaphysis, preserving the hip articulation. This solution is possible, in the case that the tumor is located in the diaphysis and does not affect the hip nor the knee. The mounting to undertake is in this case different and consists of joining the proximal intramedullar stem (9) with a diaphysis component (3) and with a distal intramedullar stem (4). The joining of these elements is obtained with transversal screws not represented in the accompanying drawings. There are three sizes of proximal intramedullar stems (9) with the same length but with different diameters.

7) The fitting of the different pieces with each other is obtained by means of male and female hexagonal screw nuts which permit 6 different positions and that immobilize the rotation of one element against the other.

8) The prosthesis have a porous coating in the following zones:

- total front surface of the metaphisary component (1) and diaphysis components (3) in order to situate the bone graft in this zone and in order to achieve the bone osteointegration with the implant.
- proximal one third portion of the intramedullar stem in order to achieve a good fixation of the implant to the bone.

9) The metaphisary component (1) is unique and its size is reduced in order that the minimum resection to undertake is small.

Resuming and as it has shown hereinabove, the prosthesis has a modular design which is adjusted to the surgeon's needs and that it joined to its high stability, its light weight. All its elements are combinable and enable to solve the majority of the cases which are presented in the case of massive osseous substitutions of the proximal femur. A combination case may be the one shown in figure 3 where a prosthesis with the utilization of both, the proximal (9) and the distal (4) intramedullar stems, is shown.

Once sufficiently described the nature of the present invention, as well as the form to put it into practice, it only remains to be added that in the whole invention and the parts of which it is compose of, it is possible to introduce changes of form, materials and disposition, provided that said alterations do not vary substantially the characteristics of the invention which are claimed as follows.

Claims

1. Osseous substitution prosthesis of modular design adequate for the osseous substitutions of the femur

proximal zone, up to the upper 2/3 of the length of the femur, characterised in that it has a metaphisary component, of one or various accumulable diaphysis components and of an intramedullar stem, and in that in order to join the metaphisary component, one or various diaphysis components and the intramedullar stem a screw which holds the prosthesis is used being screwed onto the intramedullar stem.

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2. Osseous substitution prosthesis of modular design according to the previous claim, characterised in that the metaphisary component is unique and therefore common to all interventions and in that it has a medial opening.

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3. Osseous substitution prosthesis of modular design according to claim 1, characterised in that the diaphisiary components vary in their lengths from one size to another at a very small and fixed quantity rate, or in that the maximum error that might be committed is precisely the value of that very small established quantity rate.

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4. Osseous substitution prosthesis of modular design according to the former claim, characterised in that the intramedullar stem may be of different lengths and diameters which are chosen depending on the patient's medular canal diameter and on the quality of the bone; and in that in order to improve its fixation, once introduced in the healthy bone, cortical screws are used which transversally fix a lateral tongue of the stem to the bone.

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5. Osseous substitution prosthesis of modular design according to claim 1, characterised in that there are various types of joining screws and in that the fitting of the diverse pieces with each other is obtained by means of male and female hexagonal screw nuts.

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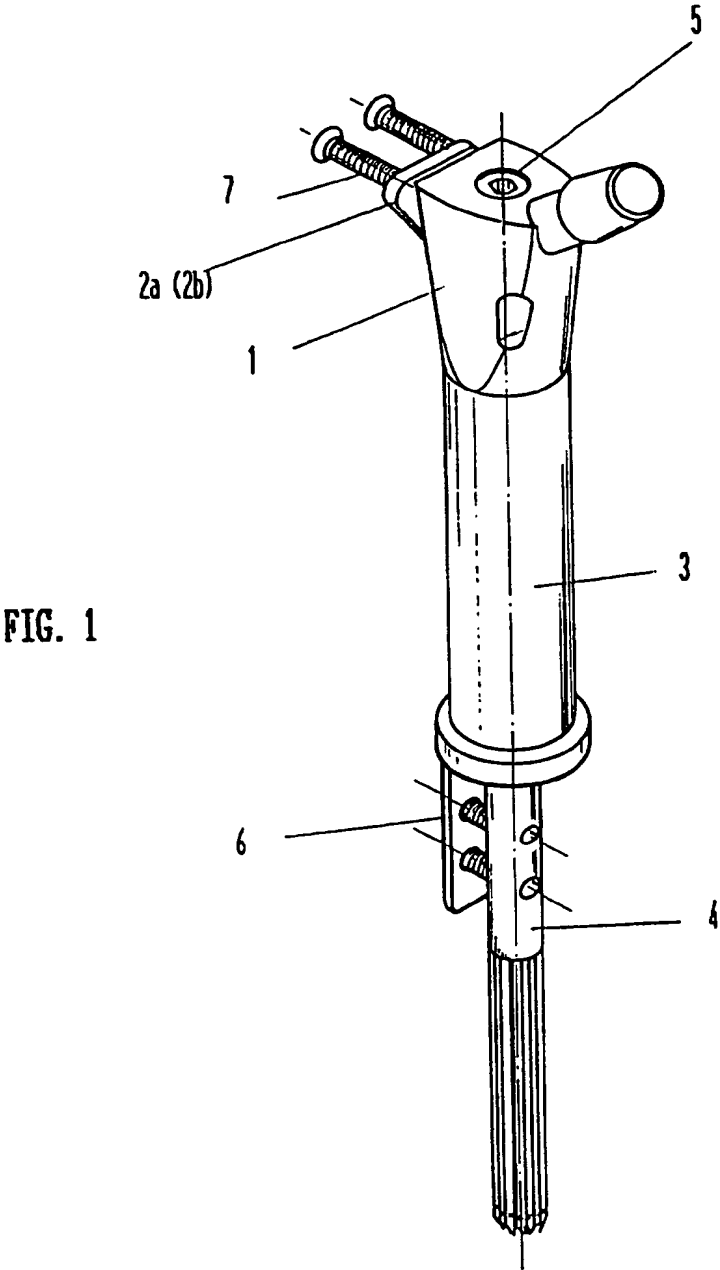
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6. Osseous substitution prosthesis of modular design according to the previous claims, characterised in that it has a porous coating on the whole external surface of the metaphisary component and of the diaphysis components, and of the proximal one-third portion of the intramedullar stem.

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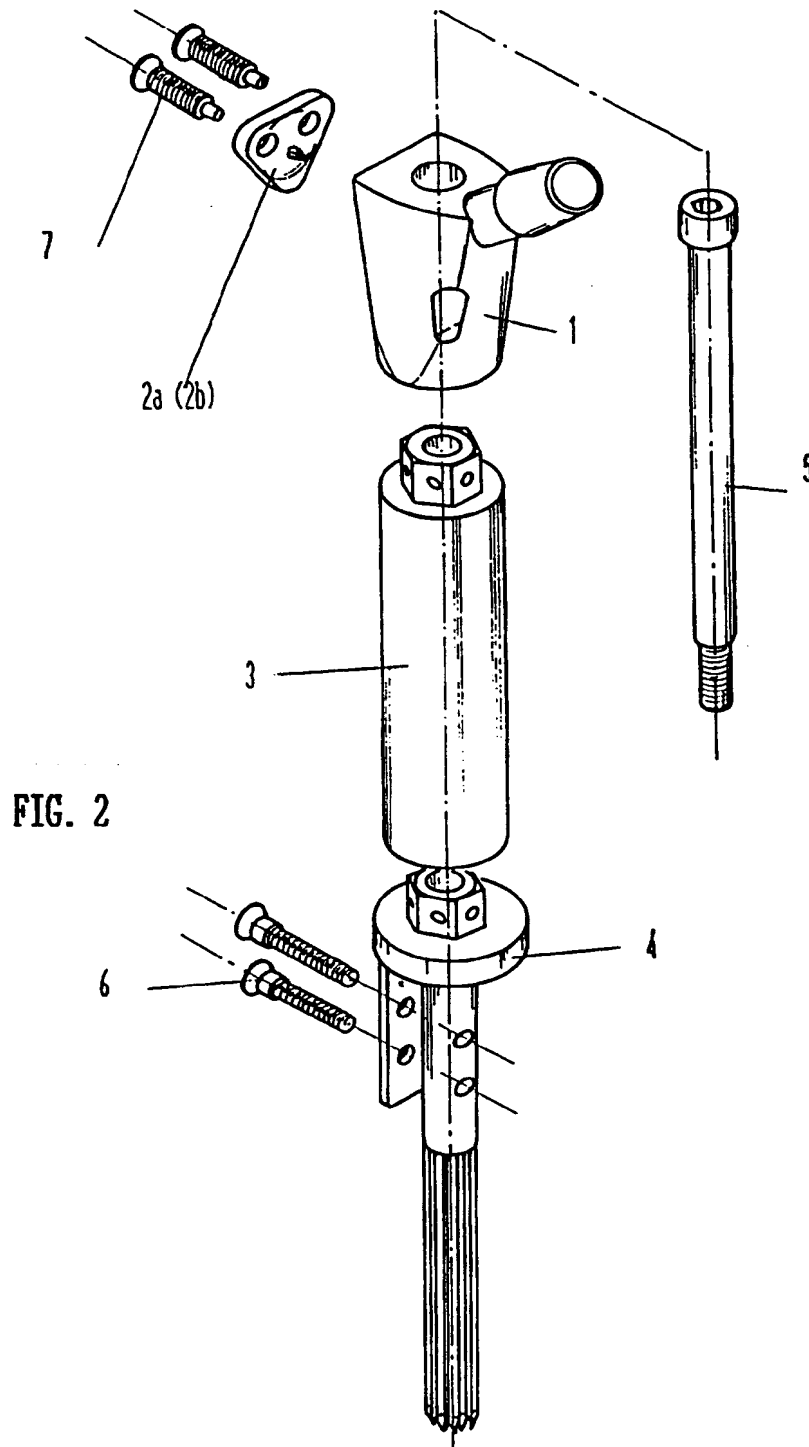
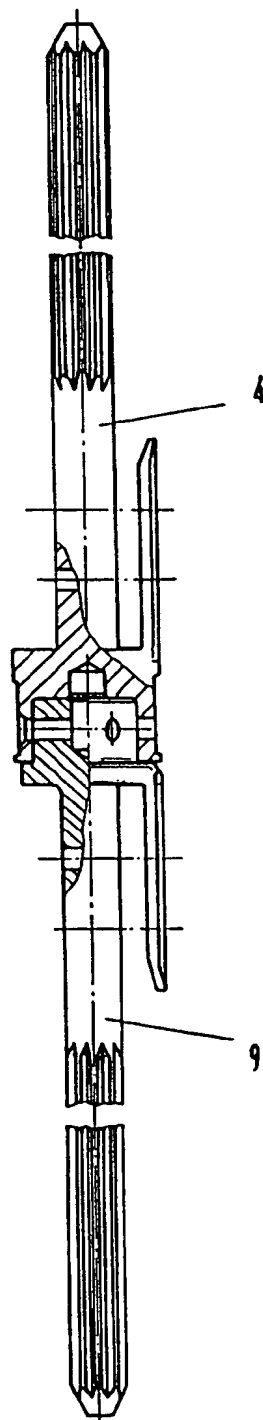
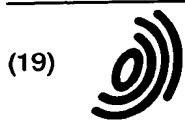


FIG. 3





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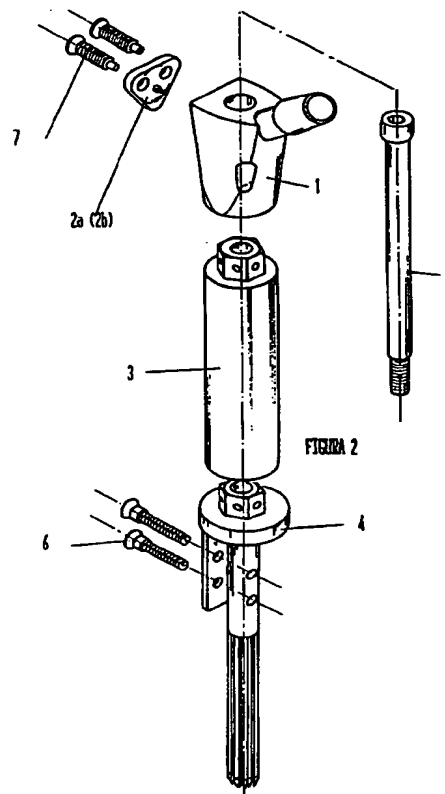
(72) Inventor: Mas Gomez, Fco. José
F-46988 Paterna, Valencia (ES)

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EUROPEAN SEARCH REPORT

Application Number
EP 95 50 0028

DOCUMENTS CONSIDERED TO BE RELEVANT			
Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (Int.Cl.6)
X	DE-A-43 20 086 (BREHM)	1,2	A61F2/36
Y	* the whole document *	3-5	
Y	EP-A-0 382 429 (SMITH & NEPHEW RICHARDS) * column 8, line 32 - column 10, line 51; figures 1-9 *	3,4	
Y	EP-A-0 382 395 (SMITH & NEPHEW RICHARDS) * column 6, line 13 - line 24; figures 9-11 *	5	
X	FR-A-2 705 558 (MEDINOV) * page 5, line 31 - page 7, line 5; figure 1 *	1,2	
X	US-A-5 002 578 (LUMAN) * column 6, line 59 - column 7, line 43; figures 5,6 *	1,2	
X	EP-A-0 243 298 (MECRON MEDIZINISCHE PRODUKTE) * abstract; figure 1 *	1,2	TECHNICAL FIELDS SEARCHED (Int.Cl.6)
A	EP-A-0 399 920 (BOUSQUET) * column 6, line 44 - column 7, line 46; figure 7 *	1,2,6	A61F
A	WO-A-94 07438 (TRONZO) * page 9, line 2 - line 8 * * page 13, line 1 - line 8 *	6	
The present search report has been drawn up for all claims			
Place of search THE HAGUE		Date of completion of the search 30 July 1996	Examiner Klein, C
<p>CATEGORY OF CITED DOCUMENTS</p> <p>X : particularly relevant if taken alone Y : particularly relevant if combined with another document of the same category A : technological background O : non-written disclosure P : intermediate document</p> <p>T : theory or principle underlying the invention E : earlier patent document, but published on, or after the filing date D : document cited in the application L : document cited for other reasons & : member of the same patent family, corresponding document</p>			

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